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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/010,244 | 12/06/2001 | Robert Sixto JR. | SYN-064 A | 5798 |
| 27316 | 7590 | 12/30/2008 | EXAMINER | |
| MAYBACK & HOFFMAN, P.A. 5722 S. FLAMINGO ROAD #232 FORT LAUDERDALE, FL 33330 | | | | EREZO, DARWIN P |
| ART UNIT | | PAPER NUMBER | | |
| 3773 | | | | |
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| 12/30/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/010,244 | SIXTO ET AL. | |
| | Examiner | Art Unit | |
| | Darwin P. Erezo | 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 September 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 and 7-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5, 7-12 and 26-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. The applicant's amendment filed on 9/15/08 has been entered into the application.

Allowable Subject Matter

2. The indicated allowability of claims 2-5, 27, 28, 31 32, 34 and 35 is withdrawn in view of the newly discovered reference(s) to Yoon. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of "disposing two thickness of body tissue substantially parallel to one another to define an intermediate plane and two opposing outside surfaces substantially parallel to said intermediate plane" is not supported by the original written description and raises the issue of new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation of “the clamping (step)”. However, there is no antecedent basis for this limitation in claim 29. Therefore, claim 30 is rendered vague and indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 4, 5, 11, 12, 26-35 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,620,452 to Yoon.

Yoon discloses a medical method comprising: providing a clip having two substantially parallel arms 16,18 (Fig. 12) each having a respective piercing portion 50 and a bridge 14 coupling the two arms; folding body tissue to form a folded portion and advancing the clip over the folded portion (Fig. 14); bending the arms toward each other (along with the piercing portions) such that the piercing portions pierce completely through the folded body tissue (Fig. 14); wherein the two arms remain substantially parallel throughout the bending step (Fig. 14); wherein a clip applier is used to deliver

the clip (col. 2, ll. 4-15); wherein the folded body tissue is being interpreted as comprising two separate tissues separated by a gap; wherein the piercing portions are releasably coupled to the arms.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,620,452 to Yoon and in view of US 5,156,609 to Nakao et al.

Yoon discloses all the limitations of the claims except for the piercing portions of the arms contacting each other. Instead, Yoon discloses the piercing portions contacting the opposite arm. However, Nakao discloses another securing means, wherein a piercing portion from one arm contacts the other piercing portion from the opposite arm (Figs. 9-10). Therefore, since the securing means of both Yoon and Nakao are art-recognized equivalents at the time the invention was, one of ordinary skill in the art would have found it obvious to substitute the means disclosed by Yoon for the means disclosed by Nakao. Furthermore, it has been held that substituting one known element for another will be obvious to one of ordinary skill in the art since it either element will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

13. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,620,452 to Yoon and in view of US 5,403,326 to Harrison et al.

Yoon discloses all the limitations of the claims except for the step of manipulating the tissue to form a fold using a grasping instrument or with the tissue being the fundus of the stomach. However, it is known in the art to use a grasper to manipulate tissue and to apply clips to the fundus of the stomach. For instance, Harrison discloses that a surgical method of applying clips to a body tissue, wherein the body tissue can be the fundus, and wherein the tissue is manipulated by a grasper 72 to compress the tissues together (Fig. 8C); wherein the method is performed by a single instrument. Therefore,

one of ordinary skill in the art would have found it obvious to modify the methodology and device of Yoon to include the steps and structures of the device of Harrison because it would allow a practitioner to manipulate a folded tissue and provide a clip to the folded tissue with a single instrument.

Response to Arguments

14. Applicant's arguments with respect to claims 1, 7-12, 26, 29, 30, 33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773